REMARKS

Claims 1-6, 8-10, and 12-27 are pending in this application. Claims 7 and 11 previously were canceled. By way of this paper, all independent claims (Claims 1, 12, & 25) have been amended to recite that the botulinum toxin administration is "per session," support for which may be found, *inter alia*, on page 22, lines 20-24. Those claims also were amended to recite that the botulinum toxin administered is less than the amount used to paralyze a muscle, support for which may be found, *inter alia*, on page 20, lines 12-15.

No new matter has been added by way of these amendments. The amendments have been made to expedite prosecution only and should not be viewed as a disclaimer. The Applicant reserves the right to pursue all unclaimed subject matter in subsequent applications.

35 U.S.C. §102 Rejections

Claims 1-6, 8-10, 12-21, and 25-27 are rejected under 35 USC 102(e) as anticipated by U.S. Patent Publication 2004/0087893 ("Kwon"), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPL.pdf, accessed on March 22, 2007). The Applicant respectfully disagrees; however, in order to expedite prosecution only, the Applicant has amended independent Claims 1, 12, and 25 to recite that the botulinum toxin administration is per session and that the botulinum toxin administered is less than the amount used to paralyze a muscle.

On page 5, the Office Action recites that the material differences the previous Office Action Response raised (e.g., per administration) were not present as claim limitations. As mentioned above, the claims have been amended to recite that the botulinum toxin administration is "per session." Additionally, the claims now also require that the botulinum toxin dose is less than the amount used to paralyze a muscle, which is not disclosed by Kwon. Kwon states that the SSP system may be used to deliver, for example, "botox toxin" to more efficiently and safely remove or reduce wrinkle formation

and skin aging.[1] Kwon makes no distinction as to whether "botox toxin" is to be administered in non-paralytic or paralytic amounts.

Indeed, a skilled artisan may be led to believe that paralytic amounts of "botox toxin" are to be administered since Kwon specifically mentions wrinkle treatment. It is well-known that muscle paralysis may occur when injecting botulinum toxin to treat wrinkles since the treatment necessarily involves relaxing the muscles underlying the wrinkles. However, as discussed in the specification and required by the amended claims, the present invention delivers botulinum toxin in amounts less than those used to paralyze a muscle.

Further, it cannot be argued that Kwon discloses the presently-claimed invention since Kwon is directed to administration using solid dissolvable perforators that optionally incorporate a drug such that the drug is released into the body upon dissolution of the solid perforators. Kwon discloses an "invention, which applies mechanical penetration of the skin, using a solid solution perforator ("SSP") system including an array of one or more needles, blades or other perforators that include a drug as part of a solid solution perforator and dissolve or undergo biodegradation relatively quickly."[2]

Further, Kwon specifically teaches away from the conventional hollow needle administration required by Claims 1 and 12 by stating that in "contrast to conventional hollow needle technologies, the SSP system includes a solid matrix of dissolvable (including meltable) or biodegradable material that optionally holds one or more selected drugs and is formed into one or more perforators."[3] "An SSP perforator can be 100 percent drug or a mixture of drugs . . . ."[4] The Office cannot ignore the limitations of present Claims 1 and 12, which require that a "solution is administered by intradermal injection or subdermal injection."

---

[1] Kwon, p. 6, [0077].
[2] Kwon, p. 1, [0010].

In describing the needs met by the invention, Kwon states "[w]hat is needed is an approach that reduces or controls the skin barriers to permit controlled introduction of one, two or more drugs, simultaneously or sequentially, and to provide prompt initiation and cut-off of drug delivery with improved efficiency and safety."[5] As amended however, the present claims require that the botulinum toxin administration is "per session" as opposed to Kwon's controlled release system. As such, Kwon cannot anticipate or render the present claims obvious either.

Claims 12-16 and 19-23 are rejected under 35 USC 102(b) as anticipated by Orloff *et al.*, *Surg*, 1999; 121(4): 410-413 ("Orloff"). The Applicant respectfully traverses this rejection. The independent claim, 12, requires that *Botulinum* toxin be administered to a location of a skin disorder and that the administration be by intradermal or subdermal injection. Orloff is directed to the treatment of vocal fold granulomas with *Botulinum* toxin "injected into 1 or both (ie, right and/or left) thyroarytenoid muscles by transcutaneous route."[6] Here, "transcutaneous" should not be confused with intradermal or subdermal since Orloff is administering to a muscle relatively deep in the body. Indeed, some "patients received supplemental injections of botulinum toxin through direct laryngoscopy when granuloma excision was performed."[7]

A skilled artisan would not consider skin granuloma and vocal fold granuloma to be the same condition subject to the same treatment. Also, Orloff teaches injection to muscles deep within the throat of a patient while the rejected claims require injection to the skin or to a skin disorder located thereon. Further, Orloff teaches that the "potential side effects of intralaryngeal botulinum toxin include breathiness of voice, dysphagia, local pain, aspiration, and decreased efficiency of the Valsalva maneuver."[8] It is unlikely that there will be much, if any, overlap in side effects when *Botulinum* toxin is

---

[3] Kwon, p. 1, [0011].
[4] Kwon, p. 1, [0011].
[5] Kwon, p. 1, [0009] & [0010].
[6] Orloff, p. 410, right column.
[7] Orloff, p. 410, right column.

administered to treat skin disorders. Most importantly, changing Orloff's administration from the larangeal area to a skin disorder (the present claims) will render Orloff unsuitable to treat vocal fold granulomas. Likewise, modifying the claimed administration from a skin disorder to the larangeal area will render the presently-rejected claims unsuitable to treat skin disorders. As such, Orloff cannot anticipate or render the present claims obvious either.

The Applicant respectfully requests reconsideration and withdrawal of all obviousness rejections.

Claim Objections

Claims 22 and 24 are objected to for depending on rejected based claims. The Applicant respectfully submits that this objection is moot as a result of this paper.

[8] Orloff, p. 412, right column.

CONCLUSION

The Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207. Should any issues remain, the Examiner is invited to contact the undersigned at (949) 623-3521.

Respectfully submitted,

Dated: 12 May 2008

/Joseph Taffy/
Joseph Taffy
Registration No. 50973
CUSTOMER NUMBER: 45,200

KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP
1900 Main Street, Suite 600
Irvine, California 92614-7319
Telephone: (949) 253-0900
Facsimile: (949) 253-0902